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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,023	04/02/2004	Salvatore V. Pizzo	5405-304	2746
20792 7590 02/05/2010 MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627				
EXAMINER				
LE, EMILY M				
ART UNIT		PAPER NUMBER		
1648				
MAIL DATE		DELIVERY MODE		
02/05/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/817,023

Applicant(s)

PIZZO ET AL.

Examiner

EMILY M. LE

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/02/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4, 16-20 and 28-35 is/are pending in the application.
- 4a) Of the above claim(s) 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 16-19 and 28-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. Claims 1-13, 15 and 21-27 are cancelled. Claims 29-35 are added. Claims 14, 16-20 and 28-35 are pending. Claim 20 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/04/2006. Claims 14, 16-19 and 28-35 are under examination.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 14, 16-19 and 28-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takesako et al.,¹ in view of Lenney et al.²

The claims are directed to the administration of an immunogen with Compound 48/80, in a pharmaceutical carrier, to a subject to induce an immune response in the subject. Claim 16, which depends on claim 14, requires the administration be parenteral. Claims 17-19, which depend on claim 14, require the immune response to be prophylactic, therapeutic and humoral, respectively. Claim 28, which depends on

¹ Takesako et al. U.S. PreGrant Pub No. 2002/0058293 A1, published 05/16/2002

² Lenney et al. Antimicrobial Action of Compound 48/80 against protozoa, bacteria and fungi. Journal of Pharmaceutical Sciences, May 1977, Vol. 66, No. 05, 702-705.

claim 14, requires the administration be mucosal. Claims 29-34 are directed to the method of claims 14, 16, 28, 17-19, respectively.

Takesako et al. teaches the administration of an immunogen in a pharmaceutical carrier, to a subject to induce an immune response in the subject. [Example 6-10, in particular.] The administration method disclosed by Takesako et al. includes parental, mucosal. Takesako et al. teaches that the immunogen has protective activity, hence, its use as a vaccine composition to induce a prophylactic, humoral and/or cellular immunity. [Paragraph 0148, in particular.]

The vaccine composition of Takesako et al. does not comprise Compound 48/80. However, Takesako et al. suggests the use of antifungal agents and antimicrobial agents with the vaccine. [Paragraph 0148, in particular.]

At the time the invention was made, Lenney et al. teaches an antimicrobial agent that is effective against protozoa, bacteria and fungi. The antimicrobial agent of Lenney et al. is Compound 48/80. [Title and Abstract, in particular.] Thus, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to use Compound 48/80 as the antimicrobial agent in the vaccine composition of Takesako et al. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to provide antimicrobial protection to the vaccine of Takesako et al. One of ordinary skill in the art, at the time the invention was made would have had a reasonable expectation of success because the addition of antimicrobial agents with pharmaceutical products is routinely practiced.

Conclusion

4. No claim is allowed.
5. To allow the entry of the rejections set forth herein, the office action is non-final.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LE whose telephone number is (571)272-0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/EMILY M LE/
Primary Examiner, Art Unit 1648

/E. M. L./
Primary Examiner, Art Unit 1648